

**BT-03™ Powered Muscle Stimulator**  
**510(k) Summary**  
**21 CFR 807.92**  
**K003896**

**1. Sponsor's name, address, telephone number, contact information, date summary prepared:**

Jean-Jacques Chatrousse, D.C.  
President, Bexley Trading, Inc.  
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San Rafael, CA 94903  
(800) 222-0866  
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Summary prepared April 19, 2002

**2. Name of the device:**

BT-03™ Powered Muscle Stimulator; Class II, Regulation: 21 CFR 890.5850; Panel and Product Code: 89 IPF

**3. Name of the predicate:**

MS-ONE Powered Muscle Stimulator  
K994065  
Cleared by FDA for marketing on 04/04/2000

**4. Description of sponsor's device:**

The BT-03 is a powered muscle stimulator that delivers low frequency current by way of external electrodes for treatment of the indicated conditions. When delivered to the surface of the skin in the region to be treated, the low frequency current stimulates nerve endings that supply skeletal and smooth muscle tissue, leading to mild contractions. The BT-03's low-frequency produces clonic muscle contractions, a muscle pumping action that mechanically exercises the targeted muscles by producing a series of muscle twitches with sufficient time for relaxation and recovery of the muscle between twitches. The clonic muscle contractions produce increased local blood circulation and immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.

The BT-03 is supplied with a single patient lead wire that has two color-coded receptacle connectors for attachment of cables from two electrodes. Sets of four junction lead wires for adhesive electrodes, four adhesive electrodes, and four plate electrodes are also provided as standard accessories with the BT-03. Four electrode covers are provided for enclosing plate electrodes during treatment, and four elastic web straps to hold the plate electrodes and covers to the patient skin, are also included.

The BT-03 base unit includes a microprocessor that automatically performs a self-test routine upon start-up, controls various functions, and monitors stimulation parameters during treatment. An intensity controller sets the stimulation current within safe limits for a period of time prescribed by the physician. A liquid crystal display enables selection of treatment modes, and displays various selected treatment parameters including time and intensity of treatment options. Other displays show the integrity of electrode placement, when current is being delivered to the patient, and system activity.

The BT-03 base unit contains a data selector knob that moves a cursor between the various display menus. An intensity control knob enables the treatment dose of applied current to be set from zero up to the maximum of 75 mA. The BT-03 is labeled with a maximum safe dose limit of 2 mA/cm<sup>2</sup> (current density), and when using the electrodes supplied as standard accessories with the BT-03, the treatment dose does not exceed 0.72 mA/cm<sup>2</sup> at the maximum setting of 75 mA.

A LymphaCard™ is required to activate the BT-03. The LymphaCard is inserted into a *card reader* on the right side of the base unit, and contains a small chip that turns on access to menu functions and stores selected treatment parameters. Six LymphaCards are supplied standard with the base unit, and each patient will have his or her own LymphaCard that, upon initiation of first treatment, is set with and stores each patient's prescribed treatment parameters.

## 5. Statement of Intended Use

The BT-03 is a powered muscle stimulator that is intended to be used to produce the following circulatory effects:

- (1) Increasing local blood circulation; and
- (2) Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.

Powered muscle stimulators should only be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions.

The intended use of the BT-03 includes only two of the six intended uses of the predicate.

## 6. Summary Comparison of Technological Characteristics

The following is a comparison of the technological characteristics between the BT-03 and the predicate:

<u>BT-03</u>	<u>Predicate</u>
Non-portable, AC powered	Portable, battery powered
Single, synchronous output mode & channel	Single, asynchronous output mode & channel
Regulated output is current	Regulated output is voltage
Microprocessor control	No software/firmware/microprocessor control
Automatic overload trip	No automatic overload trip
Automatic no-load trip	No automatic no-load trip
Automatic shut-off	No automatic shut-off
Patient override control	Patient override control
1-300 minute timer range	No timer
Conformance with FDA-recognized standard for powered muscle stimulators & others	No consensus standards conformance
Complies with patient lead wire mandatory performance standard in 21 CFR 898	Complies with patient lead wire mandatory performance standard in 21 CFR 898
Waveform is monophasic, alternating pulse polarity	Waveform is biphasic, symmetrical
Operating frequencies 1.52, 1.99 & 2 to 60 Hz adjustable.	Operating frequencies 2.04 to 58.82 Hz.
Maximum output voltage @500 Ω=37.5 V <sub>p</sub>	Maximum output voltage @500 Ω=40.8 V <sub>p</sub>
Maximum output current @500 Ω=75 mA <sub>p</sub>	Maximum output current @500 Ω=81.6 mA <sub>p</sub>
LymphaCard patient prescription access & current cut-off when current flow is interrupted	No additional features

The BT-03 is supplied with a set of four plate electrodes which are to be enclosed in wetted Viscose™ sponge covers when in contact with patient skin during use. Two pairs of color-matched, non-sterile, reusable adhesive electrodes are also supplied standard with the BT-03. The MultiStick™ reusable, conductive adhesive gel is applied to the adhesive electrode pad during manufacture. The useful life of the MultiStick adhesive gel is not specified by the manufacturer, but depends on the care of the electrodes and patient skin hygiene prior to attachment. Neither the BT-03, plate electrodes nor adhesive electrodes are intended for use during surgery. The predicate device is supplied with four adhesive electrodes, and adhesive gel is applied prior to each use.

The BT-03 has three stimulation mode settings, mild stimulation, moderate stimulation, and adjustable stimulation. The mild stimulation mode is characterized by shorter stimulation times, has a frequency of 1.99 Hz, and is used in cases of pain and sensation sensitivities and certain types of traumas and recent body lesions. The moderate stimulation mode is used for most circulation conditions, is characterized by somewhat longer stimulation times, and has a frequency of 1.52 Hz. The adjustable stimulation mode can be set at a desired frequency in the range of 2 to 60 Hz and provides longer stimulation times and variable inter-stimulation rest times. The predicate has a single therapy mode that delivers electrical stimulation at adjustable frequencies through a range that is similar to the BT-03. The predicate is indicated for treating other conditions than the BT-03 that include muscle exercise therapy. Although four adhesive electrodes are supplied with the predicate, only a single electrode can be used at a time.

## **7. Discussion of Nonclinical Data Supporting Substantial Equivalence & Conclusions**

The BT-03 base unit and accessories have been designed, tested and shown to fully meet the requirements of IEC, UL, and CAN/CSA standards (601-1, 2601-1, C22.2 No. 601.1-M90, respectively) for the safety of medical electrical equipment. The microprocessor firmware and software were designed, developed, and tested in accordance with the international consensus standard for programmable medical systems in IEC 60601-1-4. The patient lead wire conforms to the CDRH performance standard in 21 CFR 898, and the BT-03 system conforms to the FDA-recognized consensus standard in IEC 60601-2-10 for powered muscle stimulators. Risk analysis, mitigation, and control measures that reduce residual risk to none under normal conditions of use followed the consensus standards in EN 1441 and IEC 60601-1-4.

Having met the construction, test and performance requirements in these standards, it can be concluded that the BT-03 powered muscle stimulator is substantially equivalent to the predicate device in safety and performance.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

APR 24 2002

Michael Zmuda, Ph.D., RAC  
Bexley Trading, Inc.  
C/O: Z-Tecknologie, SP  
1105 Buckbrush Drive  
Folsom, CA 95630

Re: K003896

Trade/Device Name: BT-03 Powered Muscle Stimulator with Flexo Plate electrode model numbers EF10, EF50, EF 100, and EF200

Regulation Number: 21 CFR 890.5850 and 21 CFR 882.1320

Regulation Name: Powered muscle stimulator and Cutaneous electrode

Regulatory Class: Class II

Product Code: IPF and GXY

Dated: January 21, 2002

Received: January 24, 2002

Dear Dr. Zmuda:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

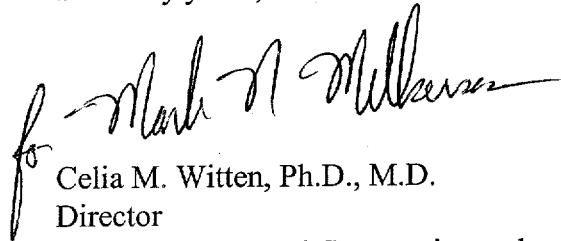
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", is written over the typed name.

Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative and  
Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**510(k) Number:** K003896

**Device Name:** BT-03 Powered Muscle Stimulator

**Indications For Use:**

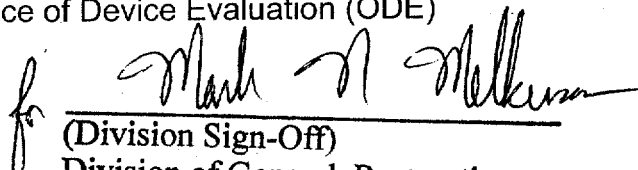
The BT-03 is a powered muscle stimulator that is indicated for use in producing the following circulatory effects:

- a. Increasing local blood circulation; and
- b. Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.

Powered muscle stimulators should only be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

510(k) Number K003896